K090680

510(K) Summary of Safety and Effectiveness

1. **Submitted By:**

John Roberts
Regulatory Affairs Specialist

JUN 10 2009

BD Medical Surgical
1 Becton Drive
Franklin Lakes, NJ 07417

Tel: 201 847 5473
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2. **Device Name:**

Trade Name: Heparin Lock Flush Solution, USP – BD PosiFlush™ Heparin Lock Flush Syringe

Common Name: Heparin Lock Flush Syringe

Classification Name: Heparin, Vascular Access Flush

3. **Predicate Device:**

Trade Name: BD Pre-Filled Heparin Lock Flush in 0.9% Sodium Chloride Injection, USP syringe
Manufacturer: Becton, Dickinson and Company
510(k) Number: K011967

Trade Name: 0.9% Sodium Chloride Injection, USP – BD Pre-Filled Flush Syringe
Manufacturer: Becton, Dickinson and Company
510(k) Number: K003553

Trade Name: Monoject Prefill Heparin Lock Flush Syringe
Manufacturer: Tyco Healthcare
510(k) Number: K013556

4. **Device Description:**

The Modified Device, the subject of this 510(k), the Heparin Lock Flush Solution, USP – BD PosiFlush™ Heparin Lock Flush Syringe uses a single use disposable Hypodermic syringe, identical to the Predicate Device (K003553), filled with USP Heparin Lock Flush Solution. The Modified Device has a sterile fluid path with an SAL of 10^{-6}.

5. **Intended Use**:

The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringes are intended for use in maintaining the patency of vascular access devices (VAD's)

10 usp units/mL and 100 usp units/mL in 3ml fill in 3ml syringe with 10ml diameter and 5ml fill in 5ml syringe with 10ml diameter

6. **Technological Characteristics:**

The Modified Device, the subject of this 510(k), the Heparin Lock Flush Solution, USP – BD PosiFlush™ Heparin Lock Flush Syringe has been modified to achieve terminal sterilization (SAL of 10^{-6}) via steam autoclave.

The Modified Device is manufactured of similiar materials and has the same intended use as the Predicate Devices.

7. **Performance:**

Design Verification tests were performed based on the risk analysis performed and results of these tests demonstrate that the Heparin Lock Flush Solution, USP – BD PosiFlush™ Heparin Lock Flush Syringe performed in an equivalent manner to the predicate devices and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Roberts
Regulatory Affairs Specialist
Becton Dickinson and Company
BD Medical Surgical
1 Becton Drive MC237
Franklin Lakes, New Jersey 07417

JUN 10 2009

Re: K090680
Trade/Device Name: Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NZW
Dated: May 12, 2009
Received: May 13, 2009

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090680

Device Name: Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringe

Indications for Use:

The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringes are intended for use in maintaining the patency of vascular access devices (VAD's)

10 usp units/mL and 100 usp units/mL in 3ml fill in 3ml syringe with 10ml diameter and 5ml fill in 5ml syringe with 10ml diameter

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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